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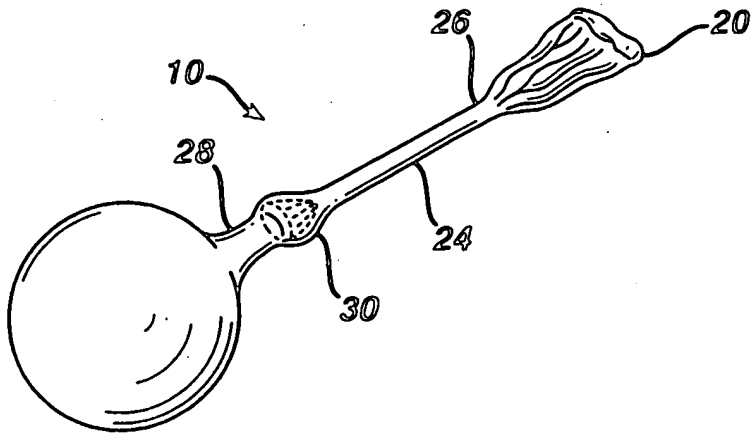
(54) Title: DEVICE FOR INSERTION INTO A BODY CAVITY



(57) Abstract: The present invention relates to an intravaginal catamenial device having a distensible member for sealingly engaging walls of a vagina. Inflating the distensible member provides immediate expansion after insertion into the vagina, thereby minimizing the potential for any by-pass leakage of bodily fluids. The device of the present invention employs a valve mechanism capable of two-way fluid communication that enables both inflation and deflation of the device. The distensible member may be of any shape that is useful for blocking and/or collecting bodily fluids.

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Device for Insertion into a Body Cavity

Cross-Reference to Related Applications

This application is related to commonly assigned, co-pending US Serial No. 09/342,544, filed June 29, 1999.

Field of the Invention

The present invention relates to an intravaginal device comprising components capable of being distended to engage vaginal walls during use and then contracted prior to its removal.

Background of the Invention

Intravaginal devices for managing bodily fluids are known in the art. Two major uses are known: managing discharged bodily fluids, such as menses, and support of the urinary system, such as "pessaries". Devices for managing bodily fluids generally fall into two main categories. The first category consists of one or more absorbing bodies such as tampons containing absorbent material. An example of a tampon and methods for making the same, are disclosed in Friese, US Pat. No. 4,816,100. Tampons are typically manufactured from a web of absorbent fibers and compressed into a cylindrical form for inserting into a user's vaginal canal, either digitally or with the assistance of an applicator.

The second category of intravaginal devices known in the art consists of collecting devices, such as those disclosed in Zoller, US Pat. No. 3,845,766 and Contente et al., US Pat. No. 5,295,984. Collection devices are designed to assume a normally open, concave configuration, with an open side facing a user's cervix. The collection

devices may be folded, or otherwise manipulated, to facilitate insertion into the vaginal canal.

Three recently published inventions relating to collection devices, comprise inflatable components for sealingly engaging the walls of the vaginal canal. They are Zadini et al., US Pat. No. 5,674,239 and PCT Pub. No. WO 99/07433, and DEKA Products Limited Partnership, PCT Pub. No. WO 99/13810. The devices disclosed in these references incorporate valves that allow pressurized air to enter the device during inflation, but do not allow the air to escape for deflating the devices. Due to this directional limitation, additional design features or techniques must be included to help in removing the devices after their useful life.

Zadini et al., US Pat. No. 5,674,239, discloses an intravaginal balloon for blood leakage prevention, with two alternative methods for removal after use. The first method disclosed consists of pulling on an attached removal means, such as a string, sufficient to decrease a transverse diameter of the balloon. The second method employs microporous material for constructing the balloon. This allows air to escape at a substantially predetermined time following inflation of the distensible member.

Zadini et al., PCT Pub. No. WO 99/07433, discloses an intravaginal balloon for blood leakage prevention. A method of deflating the intravaginal balloon consists of creating a slit in a chamber wall of the balloon with the removal string, thereby providing an escape route for carbon dioxide or suitable inflating gas.

DEKA Products Limited Partnership discloses a catamenial collector having a receptacle with a flexible hollow rim capable of inflation. The device employs tear marks along portions of a handle extending from the

receptacle, whereby portions of the device can be torn away, allowing for deflation prior to removal.

In each of these inflatable devices, the gas that escapes from the inflatable portion is not assuredly directed outside of the body. Indeed, in one or more of the Zadini embodiments, the gas may be discharged directly into the vagina. However, Osborn et al., WO 98/41179 suggests that the presence of excessive amounts of gas, including oxygen and carbon dioxide, in the vaginal canal may be undesirable. Therefore, it is desirable to ensure that discharges of such gases into the vagina is prevented. In addition, the inflatable devices that are pumped from the atmosphere may allow the user to over-inflate the devices with dangerous consequences.

Therefore, what is needed is a distensible intravaginal device that prevents discharge of potentially dangerous gases into the user's vagina and that safely limits the distension of any insertable reservoir.

What is still needed, is an intravaginal catamenial device comprising an distensible member and a single valve, the valve capable of repeated two-way fluid communication providing a means for both inflation and deflation of the device.

Summary of the Invention

The present invention relates to a device for insertion into a body cavity having a wall. The device includes an insertable reservoir that is capable of being inserted into the body cavity and distending to engage the wall of the body cavity. An external reservoir is in fluid communication with the insertable reservoir through a conduit. There is a valve associated with the conduit that is capable of alternately preventing and allowing

fluid to flow, via the conduit, from the external reservoir to the insertable reservoir and from the insertable reservoir to the external reservoir, as desired by a user. Preferably, the device contains a predetermined quantity of a working fluid. The device may be used intravaginally as a catamenial device or as a urinary system support. Additionally, the device may be useful if dimensioned to fit within a user's urethra to block unwanted urinary discharge.

The invention also relates to a method for controlling the passage of bodily discharges from a body cavity having a wall. The method includes inserting an insertable reservoir into the body cavity; transferring a quantity of fluid from an external reservoir into the insertable reservoir via a conduit; distending the insertable reservoir to engage the wall of the body cavity; operating a valve to maintain fluid in the insertable reservoir; operating a valve to permit transfer of a quantity of fluid from the insertable reservoir to the external reservoir via the conduit; and removing the insertable reservoir from the body cavity. This may be repeated, as necessary, to meet the needs of the user.

Alternatively, the method may relate to managing bodily fluids during a period of menstruation. Such a method may include the steps of inserting a catamenial device into a vaginal canal, having a wall, transferring fluid from the external reservoir into the insertable reservoir, the amount of fluid being sufficient to distend the insertable reservoir to cause it to engage the wall of the vaginal canal; maintaining the insertable reservoir in the vaginal canal for preventing passage of the bodily fluids from the vaginal canal for a duration of at least 2 hours; transferring fluid from the insertable reservoir to the external reservoir; and removing the insertable

reservoir from the vaginal canal. A device useful in this method has an insertable reservoir that is capable of being inserted into the vaginal canal and distending to engage the wall of the vaginal canal, an external reservoir, and a conduit providing fluid connection between the reservoirs. The insertable reservoir has a cervix-facing side and an opposing side, and a valve capable of alternatively preventing and allowing fluid to flow, via the conduit, from the external reservoir to the insertable reservoir and from the insertable reservoir to the external reservoir, as desired by a user, is associated with the conduit.

Brief Description of the Drawings

FIG. 1 is a perspective view of an insertable device according to the present invention wherein the working fluid is substantially contained in the external reservoir.

FIG. 2 is a schematic illustration of an insertable device according to the present invention.

FIG. 3 is a side elevation of an insertable device according to the present invention wherein the working fluid is substantially contained in the insertable reservoir.

FIG. 4 is a side elevation of an insertable device according to the present invention wherein the working fluid is substantially contained in an alternative insertable reservoir.

FIG. 5 is a schematic illustration of an alternative embodiment of the insertable device according to the present invention.

FIGS. 6A and 6B depict a sequence of steps illustrating the use of an insertable device in conjunction with an applicator.

FIG. 7 is a side elevation of an insertable device according to the present invention wherein an alternative insertable reservoir contains an absorbent tampon.

FIGS. 8A and 8B are side elevations of an insertable device according to the present invention wherein an absorbent tampon substantially surrounds an alternative insertable reservoir.

FIGS 9-11 are side elevations of several alternative embodiments of insertable devices according to the present invention wherein an absorbent tampon substantially surrounds the respective alternative insertable reservoir.

Detailed Description of the Preferred Embodiments

FIG. 1 depicts a perspective view of an insertable device 10 according to the present invention, and FIG. 2 is a schematic illustration of such a device 10. The device 10 comprises an insertable reservoir 20, an external reservoir 22, and a conduit 24 having a first end 26 in fluid communication with the insertable reservoir 20 and a second end 28 in fluid communication with the external reservoir 22. A valve 30 is located between the insertable reservoir 20 and the external reservoir 22 to control movement of a working fluid between them.

Moving the working fluid from the insertable reservoir 20 to the external reservoir 22 allows the insertable reservoir 20 contract (as shown in FIG. 1) to allow for easier insertion of the device 10 into a body cavity or removal of the device 10 from a body cavity. Moving the working fluid from the external reservoir 22 to the insertable reservoir 20 causes the insertable reservoir 20 to distend. When the insertable reservoir 20 contains substantially all of the working fluid, it distends to a predetermined shape (as shown in FIGS. 3 or 4). The working fluid employed in the device 10 may be

any suitable fluid, including liquids and gases. A representative, non-limiting list of suitable working fluids, includes aqueous liquids such as water, saline solution, douche solutions, acetic acid solutions, hydroxyethyl cellulose solutions or dispersions, and the like; polymeric liquids such as polyethylene glycols, liquid silicones as used in prostheses, and the like; nonaqueous liquids; common gases such as air, carbon dioxide, and the like; and inert gases such as nitrogen, noble gases, and the like.

The valve 30 controls the passage of fluid between the insertable reservoir 20 and the external reservoir 22. The device 10 of the present invention preferably provides for repeated distension (and contraction) of the insertable reservoir 20 within a short time period. As stated in the background section of the instant specification, collection devices comprising inflatable members currently known in the art require destructive or time delayed techniques for deflation (i.e., via tear-away portions or construction with microporous materials).

There are several benefits associated with the capability of repeated distension within a short time period. First, a user may wish to contract the insertable reservoir 20 slightly to reposition it after insertion and distension, due to a sense of discomfort in the placement. Second, the user may wish to contract the insertable reservoir 20 sufficiently to drain any bodily fluids into a disposal means, such as a toilet, and then to again distend it for additional use. Third, the user may find that the initial distension is too great and may desire to slightly reduce the pressure exerted by the insertable reservoir 20 without completely contracting.

Valves capable of two-way fluid communication include both two-way valves and releasable one-way valves.

Clamps, ball valves, stop cock valves, and gate valves are examples of two-way valves, wherein the valve may be manipulated to either an open or a closed position, but is not biased to either one of the positions. Check valves, reed valves, umbrella valves, and duckbill valves are examples of one-way valves. One-way valves are normally in a closed position, allowing pressurized fluid to flow in one direction, while resisting flow in the opposite direction. When one-way valves are used in the present invention, it is critical that they are accessible and manipulable by the user, so that the valves may be releasable, thereby providing two-way fluid communication. For example, having the capability of manually compressing the spring in a spring-loaded check valve, or compressing peripheral portions of a duckbill valve sufficient to urge normally closed sealing lips apart.

In the practice of the present invention, it may be helpful to employ a pair of oppositely disposed one-way valves (see FIG. 5). A first valve 30a would operate to maintain fluid in the insertable reservoir 20, a second valve 30b would operate to maintain fluid in the external reservoir 22. Thus, when the device 10 is manipulated to direct the fluid into the external reservoir 22, the second valve 30b would keep the fluid there (again, as shown in FIG. 1). The device 10 could then be manipulated, e.g., by compressing the external reservoir 22 and opening the second valve 30b to direct fluid from the external reservoir 22, through the conduit 24, and into the insertable reservoir 20. The first valve 30a would then keep the fluid in the insertable reservoir 20 (again, as shown in FIGS. 3 or 4).

In addition to the properties of the valve itself, a manipulable valve may also require appropriate environmental properties. As used in the Specification

and Claims, the term "environmental properties" relates to the condition or circumstances corresponding to the materials or elements of the device surrounding the valve. This includes, but is not limited to, physical properties of the valve housing and valve placement within the housing, such as depth. For example, if a duckbill valve resides within a fluid conducting conduit, then the conduit must be sufficiently flexible and resilient, in at least portions proximal the duckbill valve, so as to permit transfer of compressive forces applied to the outer surface of the conduit, to open the normally closed sealing lips. Upon release of the compressive forces, any environmental changes, such as distortion of the conduit in areas proximal the valve dissipates, due to its resiliency. This dissipation allows for repeated manipulation of valves used in the present invention.

In contrast, if a duckbill valve were residing within a rigid conduit, then compressive forces applied to outer surfaces of the rigid conduit would not be sufficiently transferable to open the normally closed lips to release fluid from the insertable reservoir 20. However, additional features in communication with the valve could render it useful. For example, such features could allow remote manipulation of the valve, or the valve could be manipulated by inserting a mechanical means, such as a rod, through the conduit and into the valve to open the normally closed lips.

The insertable reservoir 20 may be of any shape to block and/or collect discharged bodily fluids. As shown in FIG. 3, the insertable reservoir 20 has the form of a collection cup having a rim 40, a receptacle 42, and a conduit 44. The receptacle 42 has a closed end 46, and fluid channels 48 provide fluid communication from the conduit 44 through the receptacle 42 to the rim 40. In an

alternative embodiment shown in FIG. 4, the insertable reservoir 20' has the form of a substantially spherical (or, alternatively oval) balloon. Additional forms of the insertable reservoir 20 will be apparent to the ordinarily skilled practitioner. For example, those forms illustrated in Zadini et al., US Pat. No. 5,674,239 and PCT Pub. No. WO 99/07433, and DEKA Products Limited Partnership, PCT Pub. No. WO 99/13810 (the disclosures of which are herein incorporated by reference) may be used. Suitable materials for the insertable reservoir 20 include, but are not limited to elastomeric materials such as latex, silicone, polyurethanes, polyvinyl chlorides, and the like; inelastic materials such as polyester terephthalate and the like; laminates of materials such as adhesively laminated films, co-extruded films, and the like.

The external reservoir 22 may be of any shape and size appropriate to contain the working fluid prior to introduction into the insertable reservoir 20. The external reservoir 22 may be maintained under high pressure so it has a lower volume than the insertable reservoir 20, or it may have substantially the same volume as the insertable reservoir 20. The external reservoir 22 may also contain a chemical source of the working fluid that can be reacted to generate the predetermined quantity of the fluid.

In addition, the external reservoir 22 may include features that allow excess quantity of working fluid to be released from the otherwise closed system of working fluid. This would allow a user to reduce the volume occupied by the insertable device 10 during use. For example, the inserted volume may be modified by incompletely inflating the insertable reservoir 22, and the user may then expel some working fluid from the

external reservoir 22 to avoid having a partially distended external reservoir 22 from being particularly noticeable during use, prior to removal.

Finally, the external reservoir 22 may comprise several individual reservoirs or chambers within a single reservoir to allow an alternative form of customization of size in use. For example, one external reservoir 22 may be appropriate for small or young users, while moderate or average users may expel working fluid from two external reservoirs or chambers, and large and/or post-partum users may require three such reservoirs or chambers. One or more of these additional reservoirs may be removable to enhance comfort during use.

Suitable materials for the external reservoir 22 include, but are not limited to elastomeric materials such as latex, silicone, polyurethanes, polyvinyl chlorides, and the like; inelastic materials such as polyester terephthalate and the like; laminates of materials such as adhesively laminated films, co-extruded films, and the like.

The conduit 24 may be of any shape and size appropriate to provide fluid communication between the insertable reservoir 20 and the external reservoir 22 and to provide sufficient environmental features for the appropriate operation of the valve 30. The internal size and length will generally be dictated by the working fluid used and the dimensions of the body for which it is designed for use. Suitable material used for the fluid conducting conduit 24 may be similar or identical to that used for the insertable and external reservoirs, such as, without limitation, elastomeric materials such as latex, silicone, polyurethanes, polyvinyl chlorides, and the like; inelastic materials such as polyester terephthalate and the like; laminates of materials such as adhesively

laminated films, co-extruded films, and the like. Preferably, the conduit 24 is made from a flexible material to allow for comfortable use.

The system can be charged with the predetermined quantity of the working fluid through ways that will be known to those of ordinary skill in the art. Representative, non-limiting examples of these methods include (1) to inject the working fluid from a syringe or syringe-like device through a self-sealing injection port; and (2) to hold at least a portion of the inflation device under an external vacuum allowing the interior of the reservoir to be exposed to atmospheric pressure, charging the reservoir and keeping the reservoir walls extended (when sealed to the remaining elements, such as the chamber and other reservoir, the charged reservoir would contain the predetermined quantity of working fluid).

Referring to Figs. 6A-6B, the insertable device 10 may be used in combination with an applicator 60. The applicator may be custom designed for the insertable device 10 or it may be a generally cylindrical, tubular applicator having a domed insertion end 62 as used to insert tampons. The use of an applicator 60 may also provide sufficient pre-insertion restriction on the insertable reservoir 20 to substantially eliminate the need for more than one valve 30. Fig. 6A illustrates the insertable reservoir 20 in a contracted state enclosed in the applicator 60. Fig. 6B illustrates the deployment of the insertable reservoir 20 in a distended state during the withdrawal of the applicator 60. After removal of the applicator, the distended insertable reservoir 20 appears substantially the same as shown in Fig. 3.

Absorbent material may optionally be associated with the insertable reservoir for improving the fluid management capabilities of the device, such as in an

overlying position on at least a portion of the insertable reservoir's outer surface. FIG. 7 depicts an insertable reservoir 70 providing a receptacle for a singular absorbent body 72, such as a commercially available tampon. Alternative forms of absorbent bodies and materials may also be used, such as for example superabsorbent particles or fibers adhered to at least a portion of the outwardly disposed surface of the insertable reservoir 70. The use of construction adhesives well known in the industry, such as styrenic block copolymers, is one suitable method for adhering absorbent material to the distensible member. Another suitable form of absorbent material is a nonwoven web comprising a blend of cellulosic fibers such as rayon and thermoplastic fibers in an amount sufficient to provide heat sealability to the outwardly disposed surface of the distensible member. A representative, non-limiting list of useful absorbent material includes natural cellulosics, regenerated cellulosics, polyacrylates, grafted starch, grafted cellulose, and polyvinyl alcohol. Cotton, wood pulp, and peat moss are examples of natural cellulosics, while rayon is an example of a regenerated cellulosic fiber. The fibers may be generally cylindrical in their cross-section, multilimbed as disclosed in EP 301 874, flocked as disclosed in Lasko, US Ser. Nos. 09/356947 and 09/356948, and the like. A representative, non-limiting list of useful absorbent materials includes highly absorbent polymers such as superabsorbent materials, including particles and fibers, hydrogel materials, and the like; cellulosic fibers such as rayon, natural fibers such as wood pulp and cotton, and the like; synthetic, and non-cellulosic fibers such as polyolefins, polyesters, and the like.

Other alternative arrangements of insertable reservoirs and absorbent materials are illustrated in Figs. 8-11 in which the insertable reservoir is primarily contained within an absorbent body. Fig. 8A illustrates such an alternative embodiment prior to use. This embodiment includes an insertable reservoir 80 contained in an absorbent body 82, such as a tampon. Again, the insertable reservoir 80 is coupled via a conduit 84 to an external reservoir 86. After insertion into an appropriate body cavity, such as a vagina, the insertable reservoir 80 is distended to also distend a base portion 88 of the tampon. After use, the insertable reservoir 80 can again be reduced in size to allow for easier removal.

Fig. 9 illustrates another alternative embodiment in use. In this embodiment, an insertable reservoir 90 is again substantially contained within an absorbent body 92, such as a tampon. The insertable reservoir 90 extends along much of the length of the tampon 92, but the reservoir 90 is shaped to provide less radial expansion at a head portion 94 of the tampon 92 than at the base portion 96 when the working fluid is transferred from the external reservoir 98.

Fig. 10 illustrates another alternative embodiment in use. In this embodiment, an insertable reservoir 100 is again substantially contained within an absorbent body 102, such as a tampon. The insertable reservoir 100 extends along much of the length of the tampon 102, and it is shaped to provide substantially uniform expansion along the length of the tampon 102 such that the head portion 104 of the tampon 102 has substantially the same diameter as the base portion 106 when the working fluid is transferred from the external reservoir 108.

Fig. 11 illustrates yet another alternative embodiment in use. In this embodiment, an insertable

reservoir 110 is again substantially contained within an absorbent body 112, such as a tampon. The insertable reservoir 110 is primarily disposed in the head portion 114 of the tampon 112 to provide substantial expansion there. In addition, the tampon 112 has one or more projections 116 located in the head portion 114 to allow a more intimate fit with the body cavity. These projections 116 may be individual, or they may extend about the head portion 114 to form a receptacle of absorbent material when the working fluid is transferred from the external reservoir 118.

As indicated above, the device may also include additives to achieve particularly desired goals. A representative, non-limiting list of potential additives includes medicaments, moisturizers, vitamins and minerals, and odor controlling agents.

In more detail, the conduit includes at least one valve in a valve system. A preferred valve system is a pair of releasable, one-way valves. More preferably, it is a pair of one-way duckbill valves. Such valves are disclosed in Fitzpatrick et al, a commonly assigned, co-pending US Serial No. 09/342,544, filed June 29, 1999, the disclosure of which is herein incorporated by reference.

Using an insertable device of the present invention as a menstrual device a user inserts at least the inflatable reservoir into her vaginal canal. This insertion may be aided by an appropriate applicator, if necessary. She can then force fluid from the external reservoir into the inflatable reservoir. When the user is ready to remove the device, she may manipulates the valve from a closed position to an open position to allow her body to exert unresisted pressure to force at least some of the working fluid back into the external reservoir. She may choose to completely, or alternatively, partially

deflate the insertable reservoir to facilitate its easy and comfortable removal from the vaginal canal.

The valve is preferably positioned external to the opening of the user's vaginal canal. External includes positions adjacent the opening, such as within the user's labia minora and/or majora. Valve may also be positioned within the user's vaginal canal. If a pair of valves are used, it is preferred that both are preferably positioned external to the opening of the user's vaginal canal.

The insertable reservoir 20 and the external reservoir 22 may each be made by dipping a mandrel into uncured material, curing or drying the material on the mandrel, and then removing the formed distensible member from the mandrel. Alternatively, they may made by blow molding, adhering films, injection molding (including liquid injection molding), rotomolding, and the like.

The conduit 24 may be initially formed as a substantially tubular element through extrusion or injection molding techniques, or formed through secondary operations from a sheet of material. The insertable reservoir 20, external reservoir 22, the conduit 24, and the valve 30 are preferably manufactured separately and then assembled together into a final form as shown in the figures. A representative, non-limiting list of assembly techniques and materials, includes adhesives, heat seal, ultrasonic welding, solvent welding, and mechanical fastening.

While particular embodiments of the present invention have been illustrated and described, other changes and modifications can be made without departing from the spirit and scope of the invention. It is therefore intended to cover in the appended claims all such changes and modifications that are within the scope of this invention.

WHAT IS CLAIMED IS:

1. A device for insertion into a body cavity having a wall, the device comprising:

a) an insertable reservoir that is capable of being inserted into the body cavity and distending to engage the wall of the body cavity;

b) an external reservoir;

c) a conduit having a first end in fluid communication with the insertable reservoir and a second end in fluid communication with the external reservoir;

d) a valve capable of alternately preventing and allowing fluid to flow, via the conduit, from the external reservoir to the insertable reservoir and from the insertable reservoir to the external reservoir, as desired by a user.

2. The device of claim 1 wherein the device contains a predetermined quantity of a working fluid.

3. The device of claim 2 wherein the working fluid comprises a liquid.

4. The device of claim 3 wherein liquid is selected from the group consisting of liquids and gases.

5. The device of claim 4 wherein the working fluid comprises an aqueous liquid selected from the group consisting of water, saline solution, and an acetic acid solution.

6. The device of claim 4 wherein the working fluid comprises a liquid selected from the group consisting of polymeric liquids and non-aqueous liquids.

7. The device of claim 4 wherein the working fluid comprises a gas.

8. The device of claim 7 wherein the gas is selected from the group consisting of air, carbon dioxide, oxygen, nitrogen, noble gases, inert gases, and a mixture of two or more gases.

9. The device of claim 1 wherein the insertable reservoir is dimensioned to fit into a human vagina.

10. The device of claim 9 wherein the insertable reservoir comprises a shaped feature arranged and configured to accept and contain bodily discharges.

11. The device of claim 10 wherein the shaped feature comprises a receptacle.

12. The device of claim 9 wherein the insertable reservoir comprises a shaped feature to provide physical support to a user's urinary system.

13. The device of claim 1 wherein at least a portion of the insertable reservoir is dimensioned to fit intimately within an interlabial region proximate a user's vagina.

14. The device of claim 1 wherein the insertable reservoir is dimensioned to fit into a human urethra.

15. The device of claim 1 wherein the valve is capable of repeated two-way fluid communication.

16. The device of claim 1 which further comprises a second valve associated with the conduit.

17. The device of claim 1 wherein at least portions of the conduit proximal the valve are flexible and resilient.

18. The device of claim 1 further comprising absorbent material associated with outwardly disposed surfaces of the insertable reservoir.

19. A catamenial device for insertion into a vaginal canal having a wall, the device comprising:

a) an insertable reservoir that is capable of being inserted into the vaginal canal and distending to engage the wall of the vaginal canal, the insertable reservoir having a cervix-facing side and an opposing side;

b) an external reservoir;

c) a conduit having a first end in fluid communication with the insertable reservoir extending from the opposing side and a second end in fluid communication with the external reservoir;

d) a valve capable of alternatively preventing and allowing fluid to flow, via the conduit, from the external reservoir to the insertable reservoir and from the insertable reservoir to the external reservoir, as desired by a user.

20. The catamenial device of claim 19 wherein the insertable reservoir comprises a shaped feature on its cervix-facing side arranged and configured to accept and contain bodily discharges.

21. The catamenial device of claim 20 wherein the shaped feature comprises a receptacle.

22. The device of claim 19 further comprising absorbent material associated with outwardly disposed surfaces of the insertable reservoir.

23. A method for controlling the passage of bodily discharges from a body cavity having a wall comprising the steps of:

a) inserting an insertable reservoir into the body cavity;

b) transferring a quantity of fluid from an external reservoir into the insertable reservoir via a conduit having a first end in fluid communication with the insertable reservoir and a second end in fluid communication with the external reservoir;

c) distending the insertable reservoir to engage the wall of the body cavity;

d) operating a valve to maintain fluid in the insertable reservoir;

e) operating a valve to permit transfer of a quantity of fluid from the insertable reservoir to the external reservoir via the conduit; and

f) removing the insertable reservoir from the body cavity.

24. The method of claim 23 wherein the step of transferring a quantity of fluid from the external reservoir into the insertable reservoir comprises compressing the external reservoir.

25. The method of claim 24 which further comprises operating a valve to permit fluid to be transferred from the external reservoir.

26. A method of managing bodily fluids during a period of menstruation, comprising the steps of:

a) inserting a catamenial device into a vaginal canal, having a wall, the device comprising:

i) an insertable reservoir that is capable of being inserted into the vaginal canal and distending to engage the wall of the vaginal canal, the insertable reservoir having a cervix-facing side and an opposing side;

ii) an external reservoir;

iii) a conduit having a first end in fluid communication with the insertable reservoir extending from the opposing side and a second end in fluid communication with the external reservoir; and

iv) a valve capable of alternatively preventing and allowing fluid to flow, via the conduit, from the external reservoir to the insertable reservoir and from the insertable reservoir to the external reservoir, as desired by a user;

c) transferring fluid from the external reservoir into the insertable reservoir, the amount of fluid being sufficient to distend the insertable reservoir to cause it to engage the wall of the vaginal canal;

d) maintaining the insertable reservoir in the vaginal canal for preventing passage of the bodily fluids from the vaginal canal for a duration of at least 2 hours;

e) transferring fluid from the insertable reservoir to the external reservoir; and

f) removing the insertable reservoir from the vaginal canal.

27. The method of claim 26 wherein the step of transferring fluid from the insertable reservoir to the external reservoir comprises manipulating at least one valve to permit fluid to be transferred from the insertable reservoir.

FIG. 1

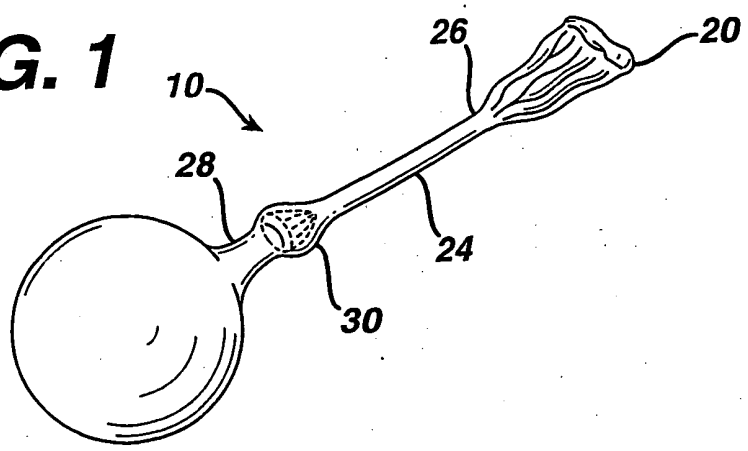


FIG. 2

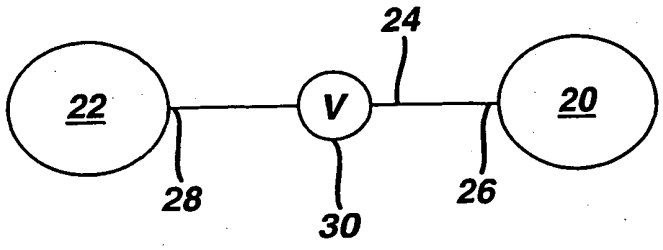


FIG. 3

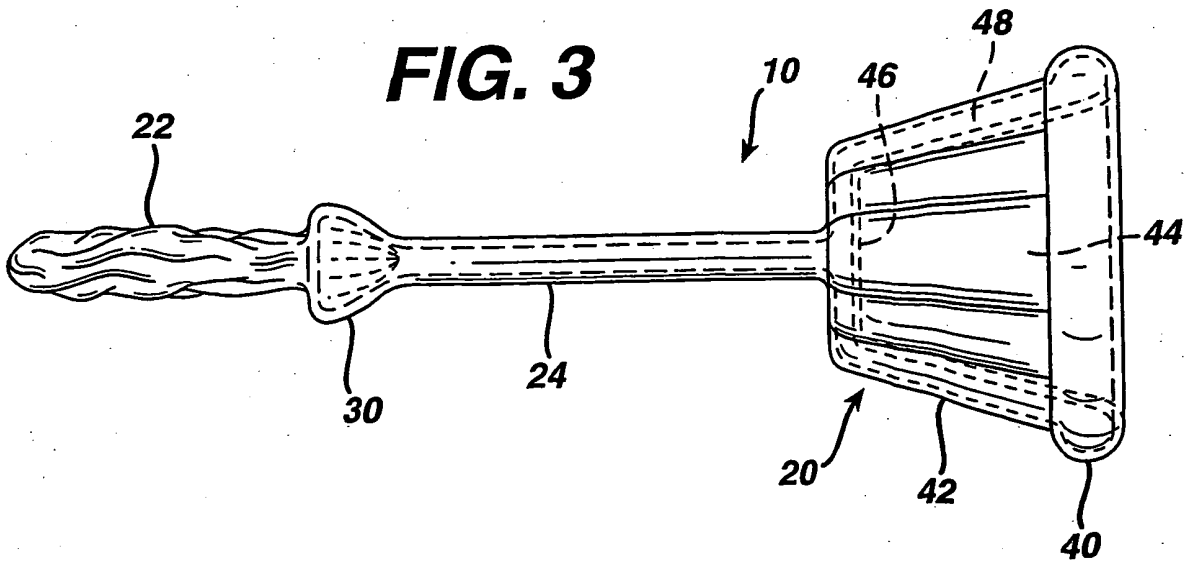


FIG. 4

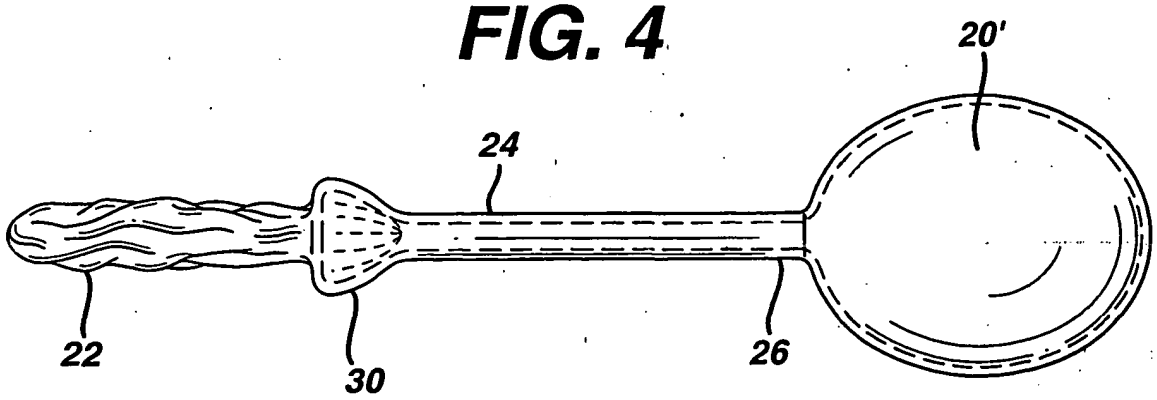


FIG. 5

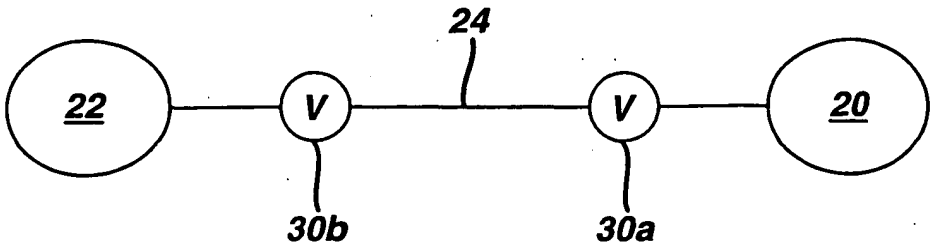


FIG. 6A

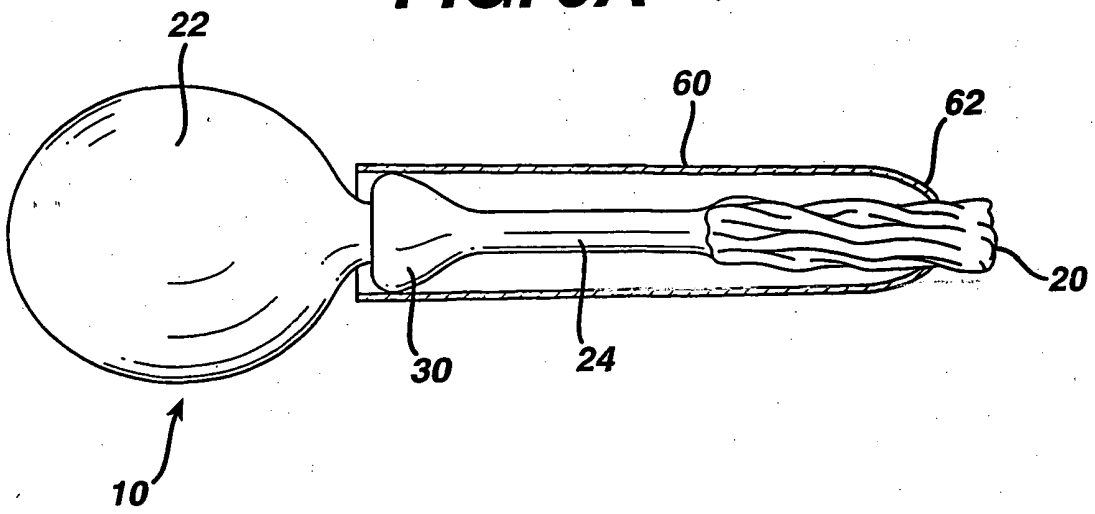
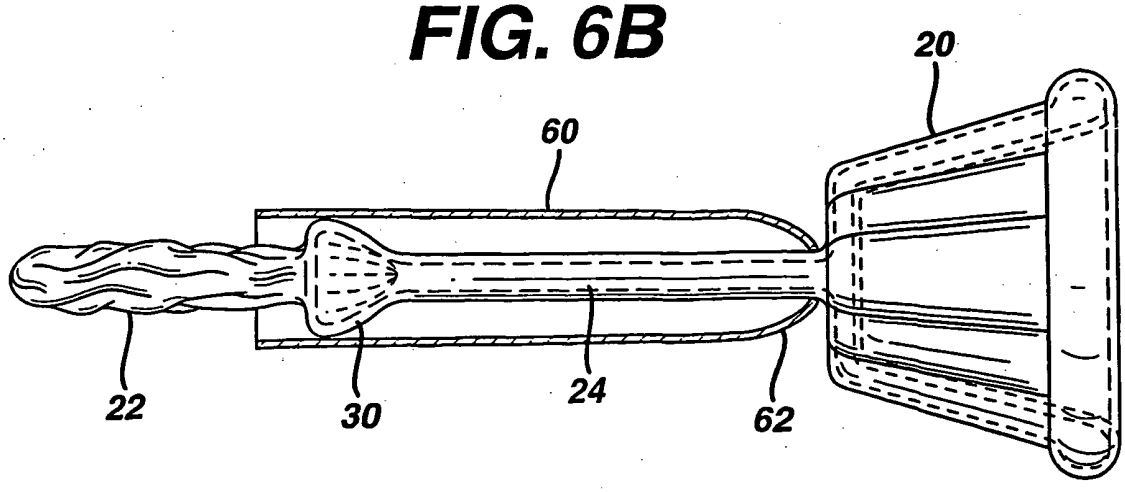


FIG. 6B



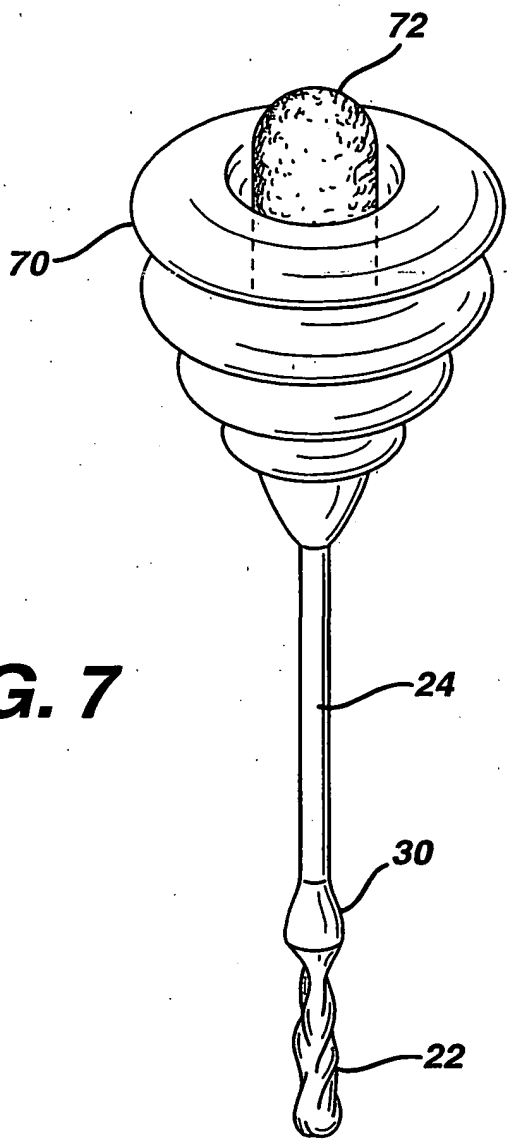


FIG. 7

FIG. 8A

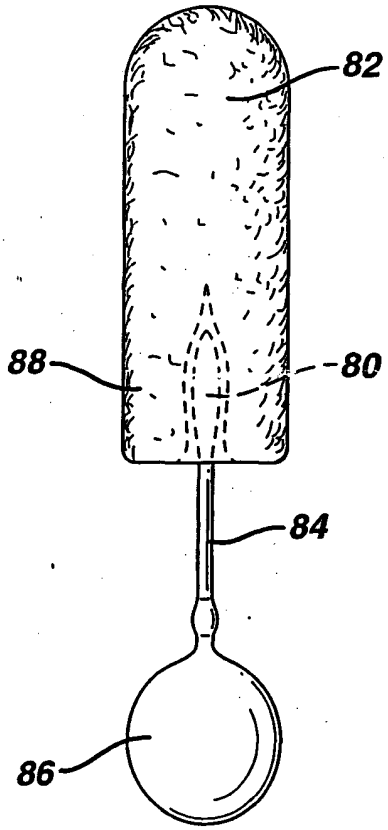
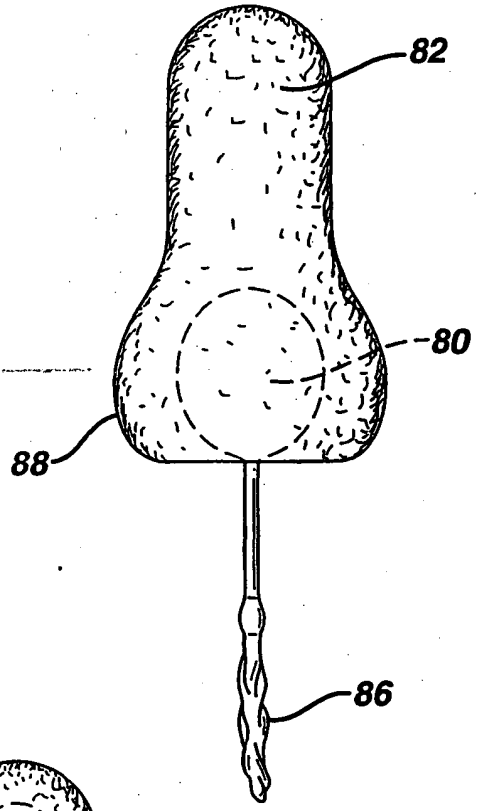


FIG. 8B



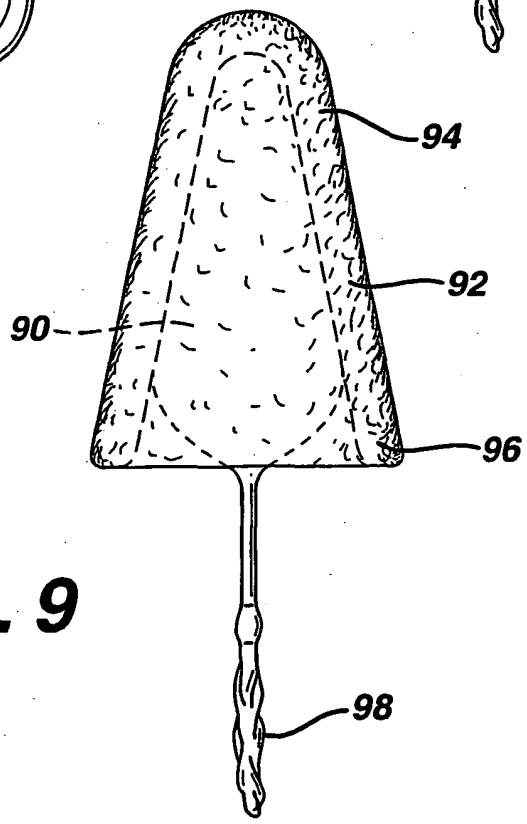


FIG. 9

FIG. 10

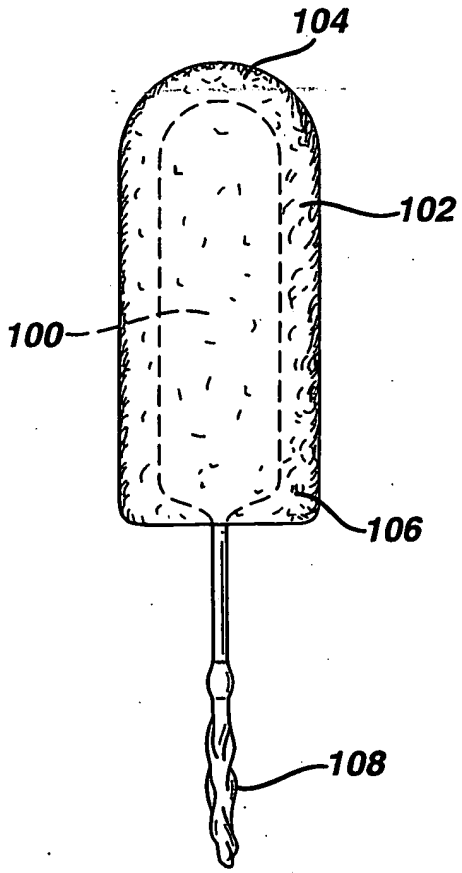
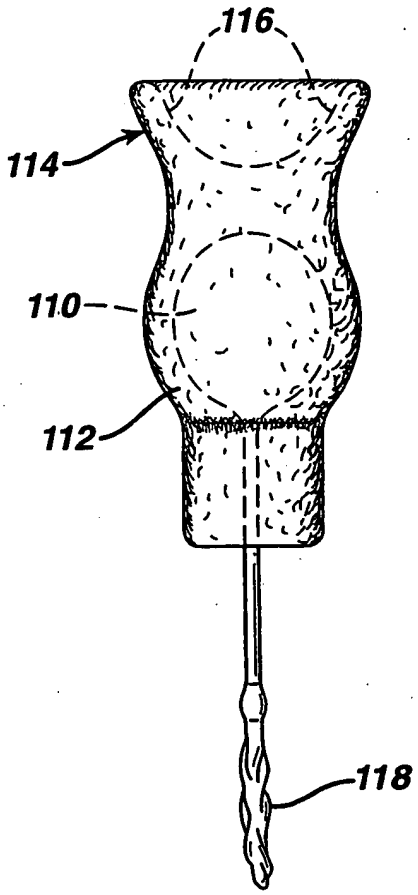


FIG. 11



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(71) Applicant: MCNEIL-PPC, INC. [US/US]; Grandview Road, Skillman, NJ 08558 (US).

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(74) Agents: JOHNSON, Philip, A. et al.; Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08933 (US).

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Published:
— *with international search report*

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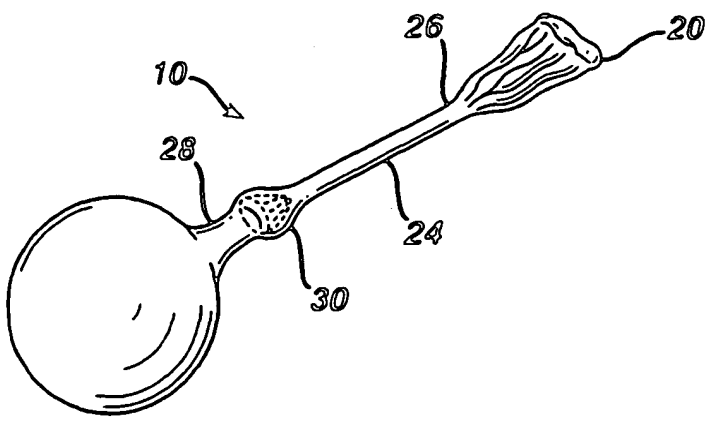
6 June 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DEVICE FOR INSERTION INTO A BODY CAVITY



(57) Abstract: The present invention relates to an intravaginal catamenial device having a distensible member for sealingly engaging walls of a vagina. Inflating the distensible member provides immediate expansion after insertion into the vagina, thereby minimizing the potential for any by-pass leakage of bodily fluids. The device of the present invention employs a valve mechanism capable of two-way fluid communication that enables both inflation and deflation of the device. The distensible member may be of any shape that is useful for blocking and/or collecting bodily fluids.

WO 02/00148 A3

INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/US 01/18524

A. CLASSIFICATION OF SUBJECT MATTER
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2 769 442 A (GEORGE STUBBS) 6 November 1956 (1956-11-06)	1-17, 19-21, 23-27
Y	column 1, line 15 -column 2, line 59; figures	18,22
Y	US 5 674 239 A (ZADINI FILIBERTO P ET AL) 7 October 1997 (1997-10-07) cited in the application column 4, line 26 - line 31 column 4, line 46 - line 49; figures 4,2	18,22
A	EP 0 663 197 A (HAMMERSEN ECKEHARD DR) 19 July 1995 (1995-07-19)	

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Date of the actual completion of the international search	Date of mailing of the international search report
17 December 2001	27/12/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Sánchez y Sánchez, J

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. ional Application No
PCT/US 01/18524

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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